

# Exhibit 8

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

**IN RE: JOHNSON & JOHNSON TALCUM  
POWDER PRODUCTS MARKETING, SALES  
PRACTICES, AND PRODUCTS LIABILITY  
LITIGATION**

ANNE CARTER JUDKINS,

Plaintiff,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

MDL NO. 16-2738 (FLW) (LHG)

Civil Action No.3:18-cv- 17586-FLW-LHG

EXPERT REPORT OF CHERYL C. SAENZ, M.D.

Case-specific opinions regarding Ms. Anne Carter Judkins

Date: May 28, 2024

  
Cheryl C. Saenz, M.D.

## Case-specific opinions regarding Ms. A. Carter Judkins

### Diagnosis and Treatment of Ovarian Cancer

Carter Judkins was born on September 19, 1956. In November 2016, Ms. Judkins presented to Dr. Michelle Urban with complaints of difficulty urinating and feeling as though she had a full bladder with urinary frequency and small voids. Her symptoms had been ongoing for 1-2 weeks. She denied dysuria and reported that she had bladder infections in the past with different symptoms. Her examination and symptoms were thought to be most consistent with a cystocele and she was sent for imaging. Pelvic ultrasound performed on December 15, 2016 revealed a large 11.1 x 7.7 x 10.0 cm mass in the midline of the pelvis, with hypervascularity and solid and cystic components. There was also noted to be a moderate amount of free fluid in the cul-de-sac. The same day, a CT scan was performed of the abdomen and pelvis, and that study identified a 10cm complex solid and cystic mass in the pelvis consistent with an ovarian neoplasm. As a result of these abnormal findings, Ms. Judkins was referred to Gynecologic Oncology at Dartmouth-Hitchcock Medical Center. On December 27, 2016, she was seen for her initial consultation by Dr. Loyd West, who recommended that she be taken to the operating room for surgical exploration.

On December 30, 2016, Ms. Judkins was taken to the OR by Dr. West and underwent an exploratory laparotomy with bilateral salpingo-oophorectomy, total abdominal hysterectomy, pelvic peritoneal biopsies, pelvic and para-aortic lymphadenectomy, omental biopsies and fulguration of implants along the sigmoid epiploica. Final pathology revealed a high-grade serous carcinoma originating in the right ovary with surface involvement and extension into the paratubal soft tissue, and the findings of metastatic disease in a resected pelvic sigmoid adhesion. As the remainder of the tissues that were removed at the staging operation were negative for disease, she was reported to have Stage IIB disease. These findings were explained to Ms. Judkins by Dr. West at the time of her postoperative visit on January 13, 2017. She was counseled to be treated with IV/IP cisplatin/paclitaxel and had an intraperitoneal port placed laparoscopically on January 30, 2017. Ms. Judkins was 60 years old at the time of her diagnosis.

Ms. Judkins received her first cycle of chemotherapy on February 14, 2017. Overall, she tolerated the chemotherapy well. The dose of paclitaxel had to be reduced significantly prior to cycle 2, however, as she experienced an increase in her liver function tests to four times the upper limits of normal. She completed her 6<sup>th</sup> cycle of chemotherapy on June 7, 2017. Her chemotherapy treatments were prescribed by Dr. Ivy Wilkinson-Ryan. Ms. Judkins has remained in remission from her ovarian cancer diagnosis since completing her chemotherapy for six years, according to her most recent clinic visit with Dr. Wilkinson-Ryan's on June 26, 2023.<sup>1</sup> Dr. Wilkinson-Ryan testified that she is cautiously optimistic about Ms. Judkins' prognosis and states that "something like about 60 percent of patients who are going to recur, recur within two years, maybe 80-something percent recur within three years. And so the

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<sup>1</sup> JudkinsC\_NCCC\_C\_MDR000194.

further away you get, the less likely you are to recur. Five years, we call it a cure.”<sup>2</sup> Ms. Judkins’ clinic visits with Dr. Wilkinson-Ryan were spread out to annual surveillance examinations at the five-year disease-free mark.<sup>3</sup> On December 5, 2023, Ms. Judkins saw her primary care provider Elisabeth Jeffcote, APRN, who noted in the medical records that Ms. Judkins’ ovarian cancer is in remission and Ms. Judkins is “[f]ollowed yearly by oncology DHCM.”<sup>4</sup>

### Clinical Cancer Genetics

On September 11, 2017, Ms. Judkins met with Carol Walsh, MS, LGC and had a medical genetics consultation. Ms. Judkins reported that her paternal great aunt was deceased from breast cancer, and although during the consultation she did not report an age of onset, a medical record dated September 6, 2017, records an age of onset in her 60’s. This record also includes documentation that there was also a paternal aunt who was deceased from breast cancer.

Based on her personal history of ovarian cancer, Ms. Walsh counseled Ms. Judkins that her risk of carrying a gene mutation was high enough to justify genetic testing. Ms. Walsh recommended that Ms. Judkins be screened for germline mutations, and recommended additional sequencing of her tumor, which would be able to identify somatic mutations, and determine if the tumor has homologous recombination deficiency. In November 2017, Ms. Judkins was informed that she was negative for a germline mutation in 24/25 genes tested, however, a variant of unknown significance was detected in the PTEN gene. The counselor told her that “[i]t is unclear at this time whether the PTEN variant of uncertain significance identified...is a cancer associated mutation or is a benign change in the gene with no increased risks.” Ms. Carter was further counseled as follows: “[b]ecause the genetic basis, if any, of the ovarian cancer in Carter has not been identified, this negative result does not necessarily mean that her cancer was sporadic (i.e. not attributable to an inherited predisposition). This is because of two important limitations of the test. First, not all inherited predisposition to cancer is attributable to these 25 genes. Research has identified other genes that when mutated can increase one’s risk of cancer. Second, a small percentage of mutations in genes tested by this panel may be missed by current technology.”<sup>5</sup> On February 7, 2018, Myriad Labs reported that Ms. Judkins’ tumor demonstrated genomic instability associated with homologous recombination deficiency, meaning that she may be a candidate for future treatment with a PARP inhibitor. Additional cancer family history has been disclosed by Katherine Downs, Ms. Judkins’ sister, and she states that they have a grandmother who was diagnosed with pancreatic cancer, as well as a paternal first cousin who was diagnosed with prostate cancer.<sup>6</sup> On the maternal side, Ms. Judkins reports in deposition testimony that she has a maternal uncle

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<sup>2</sup> January 14, 2021 Deposition Transcript of Ivy Wilkinson-Ryan, p. 84.

<sup>3</sup> JudkinsC\_NCCC\_C\_MDR000198.

<sup>4</sup> JudkinsC-WHPIMR-00220-00221

<sup>5</sup> JudkinsC-DHMCMR-00575

<sup>6</sup> May 11, 2021 Deposition Transcript of Katherine Downs, p. 41.

and a grandfather, each with either bladder or kidney cancer. She herself was unsure as to which organ was affected in which individual.<sup>7</sup>

**Past Medical History**

- Basal cell carcinoma of the skin
- Eustachian tube abnormality
- Mixed hearing loss
- Lichen sclerosus
- Pyloric stenosis
- Scoliosis
- Alcohol abuse

**Past Surgical History**

- Tonsillectomy and adenoidectomy
- Tympanoplasty
- Laparotomy with pyloroplasty
- Exploratory laparotomy, TAH/BSO, omentectomy, peritoneal biopsies, para-aortic and pelvic lymphadenectomy, fulguration of epiploic implants
- Placement of intraperitoneal port

**Obstetrical/Gynecologic History**

- Menarche at age 12/13
- Menopause at ~ age 48-50
- G3P3 with first child at age 33
- Breastfeeding – 1-1 ½ year with each child
- Oral contraceptives – ~ 4 years perimenopausally starting at age 48
- Use of diaphragm and cervical cap starting in ~ 1987
- Hormone replacement therapy - none

**Summary**

I have performed a thorough review of Ms. Judkins' medical records, the depositions of A. Carter Judkins, Ivy Wilkinson-Ryan, M.D., Loyd West, M.D., Daniel Frehner, Paul Frehner, Benjamin Frehner, Bria Frehner and Katherine Downs, as well as the Plaintiff Profile Forms, the expert reports of Drs. Godleski and Wolf, and the depositions of Dr. Wolf.

Ms. Judkins was diagnosed with Stage IIB high grade serous carcinoma of the right ovary in December 2016. With appropriate surgery and an optimal debulking by Dr. West, followed by aggressive chemotherapy as prescribed by Dr. Wilkinson-Ryan, Ms. Judkins' cancer entered remission and she has remained disease-free for at least six years. Even though Ms. Judkins had negative germline testing of 24 genes with a variant of unknown significance in the PTEN gene on the Ambry panel, Ms. Judkins may carry a germline mutation that we have yet to

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<sup>7</sup> December 1, 2020 Deposition Transcript of Anne Carter Judkins, p. 91-92.

identify that contributed to her development of ovarian cancer. Most likely, Ms. Judkins' ovarian cancer developed sporadically, with no distinct causal mechanism that can be identified.

While Ms. Judkins states that she used baby powder daily from 1970-2016 for hygiene purposes, there is no credible scientific data to support that the talc contributed to her development of ovarian cancer. Dr. West, one of her treating gynecologic oncologist concurs, stating in deposition testimony that he read a review article on the topic of talc and an association with ovarian cancer and "that the gist of the article was that there is no good science involved in the association because, one, ovarian cancer is a relatively rare disease, and...my take-home from that article was there was no definite association of causation with talcum to ovarian cancer, but that the risk might be slightly increased, but the data was very poor...".<sup>8</sup>

Dr. Wolf cites to Dr. Godleski's report as supporting her contention that the perineal application of talc caused Ms. Judkins to develop ovarian cancer. In Dr. Godleski's report he states that he found birefringent particles, which likely represent talc in Ms. Judkins' left ovary and right pelvic lymph node. Importantly, neither of these organs had cancer in them. The cancer was found solely in Ms. Judkins' right ovary and right paratubal soft tissues – which Dr. Godleski did not even include in his analysis. If the talc is causing the ovarian cancer, shouldn't it be found in the organ that actually has the cancer – the right ovary? This lack of concordance between where the cancer actually is and where Dr. Godleski states he found talc particles demonstrate how the clinical findings simply do not support plaintiff's hypothesis. Additionally, even in the areas in which Dr. Godleski states he found talc particles – the left ovary, cervix and left pelvic lymph node, there is no evidence of an inflammatory response.

In her reports and in testimony, Dr. Wolf states that she has performed a differential diagnosis and concluded that Ms. Judkins' ovarian cancer was caused by the perineal application of talc because she cannot identify that Ms. Judkins had any of the established risk factors for ovarian cancer. To attribute causation to any of the risk factors associated with the development of ovarian cancer is scientifically unsound as the mechanism of disease development has yet to be elucidated. While it is true that germline mutations, incessant ovulation, hormone replacement therapy and family history are all positively associated with the development of ovarian cancer, there is not a causal role attributed to any of these risk factors, just as any of the factors known to decrease the risk of ovarian cancer cannot be attributed with a preventative role (e.g., BTL, use of OCPs, etc.). Women who seem to have none of the risk factors for ovarian cancer can and do get the disease, and likewise, women who seem to have all of the factors that decrease the risk of disease development can and do develop ovarian cancer. These factors are merely associations and how the actual disease develops, and why these factors are either positively or negatively associated with the development of ovarian cancer, are all still hypotheses. Dr. Wolf has fallen into the same trap that many of our patients fall into. They simply want an explanation as to why they developed ovarian cancer. Since she cannot identify the "reason"

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<sup>8</sup> January 28, 2021 Deposition Transcript of Loyd West, MD, p. 26.

for Ms. Judkins' ovarian cancer, she is attributing it to the use of baby powder products. Sound medical judgment does not function in this manner.

**Conclusion**

There is no credible scientific data that talc increases a woman's risk of developing ovarian cancer. It is my opinion that Ms. Judkins' ovarian cancer is not at all related to her use of talc. The peer-reviewed scientific literature, nationally recognized and respected healthcare organizations (NCI, CDC, ACS, FDA), and the professional societies (SGO, ACOG) to which I belong, all maintain the same position. All of the opinions herein are to a reasonable degree of medical probability. In addition, all of the general causation opinions contained in my Expert Report dated May 21, 2024 are incorporated herein.



**MATERIALS RELIED ON AND CONSIDERED BY DR. CHERYL SAENZ****PLAINTIFF PROFILE FORMS**

1. Plaintiff Profile Form of A. Carter Judkins
2. First Amended Plaintiff Profile Form of A. Carter Judkins
3. Second Amended Plaintiff Profile Form of A. Carter Judkins
4. Third Amended Plaintiff Profile Form of A. Carter Judkins

**DEPOSITION TRANSCRIPTS**

1. 12/01/2020 Deposition Transcript of Anne Carter Judkins
2. 01/14/2021 Deposition Transcript of Ivy Wilkson-Ryan, MD
3. 01/28/2021 Deposition Transcript of Lloyd West, MD
4. 05/03/2021 Deposition Transcript of Daniel Frehner
5. 05/03/2021 Deposition Transcript of Paul Frehner, PsyD
6. 05/05/2021 Deposition Transcript of Benjamin Frehner
7. 05/05/2021 Deposition Transcript of Bria Frehner
8. 05/11/2021 Deposition Transcript of Katherine Downs
9. 09/13/2021 Deposition Transcript of Judith Wolf, MD (Vol. 1)
10. 09/14/2021 Deposition Transcript of Judith Wolf, MD (Vol. 2)
11. 01/10/2024 Deposition Transcript of Judith Wolf, MD
12. 04/25/2024 Deposition Transcript of Judith Wolf, MD

**EXPERT REPORTS**

1. 06/18/2021 Expert Report of John Godleski, MD
2. 07/02/2021 Expert Report of Judith Wolf, MD
3. 11/15/2023 Amended Rule 26 Expert Report of Judith Wolf, MD

**MEDICAL RECORDS**

1. Ambry Genetics (JudkinsC-AGMR-00001-00079)
2. Bradley Arrick, MD (JudkinsC-ArrickB-00001-00036)
3. Atlantic Digestive Specialists (JudkinsC-ADSMR-00001-00015; JudkinsC-ADSPB-00001-00004)
4. Baystate Health (JudkinsC-BSHMR-00001-00020; JudkinsC-BSHPath-00001-00003)
5. Catholic Medical Center (JudkinsC-CMCMR-00001-00017)
6. CVS Caremark (JudkinsC-CVSCaremarkIncCorpOffice-00001-00005; JudkinsC-CVSP-00001-00007)
7. Dartmouth Hitchcock Clinic (JudkinsC-DHCMR-00001-00366)
8. Dartmouth Hitchcock Medical Center (JudkinsC-DHMCMR-00001-00981; JudkinsC-DHMCMR-01069-01076; JudkinsC-DHMCMR-01114-01157; JudkinsC-DHMCPath-

- 00001-00008; JudkinsC-DGODHMC MR-00001-00370; JudkinsC-DHNL MR-00001-00026)
9. Harbour Women's Health (JudkinsC-HarbourWomensHealthMR-00001-00064; JudkinsC-HWHMR-00065-00101, JudkinsC-HWHPB-00022-00035, JudkinsC-HWHPB-00039-00040)
  10. Jaffrey Family Medicine (JudkinsC-JFMMR-00001-00033)
  11. Jones, Rebecca, MD (JudkinsC-JonesRMMD-00001-00014)
  12. LabCorp Raritan (JudkinsC-LCR-00001-00021)
  13. Monadnock Family Care (JudkinsC-MFCMR-00001-00097)
  14. Monadnock Hospital (JudkinsC-MHMR-00001-01408)
  15. Monadnock OBGYN (JudkinsC-MOBGYN-MR-00001-00011)
  16. Daniel Morrison, MD (JudkinsC-MorrisonD-00001-00099)
  17. Myriad Genetics (JudkinsC-MGMR-00001-00032)
  18. North Meadow Family Health (JudkinsC-NMFHMR-00001-00012)
  19. OB GYN Specialists Bedford (JudkinsC-OGSBMPMR-00001-00107)
  20. Plaintiff Produced Medical Records (JUDKINSC\_DHMC\_C\_MDR000001-422; JUDKINSC-DHMC-MDR-00001-00272; JUDKINSC\_CHMC\_C\_MDR-00423-455; JUDKINSC-HWH-C-MDR00001-00012; JUDKINSC\_MCH\_C\_MDR00001-00063; JUDKINSC\_JONES\_MDR000001-12; JUDKINSC\_MFC\_C\_MDR000001-98; JUDKINSC\_NCCC\_C\_MDR000001-191; JUDKINSC\_REC000001-9; JUDKINSC\_NCCC\_C-MDR000192-204)
  21. Joshua Rifkind, MD (JudkinsC-RifkindJ-00001-00019)
  22. Paul Righi, MD (JudkinsC-RighiP-00001-00013)
  23. Rite Aid (JudkinsC-RACO-00001-00005)
  24. Seacoast Dermatology (JudkinsC-SDMR-00001-00052)
  25. Serena Shomody, DPM (JudkinsC-ShomodyS-00001-00008)
  26. Wentworth Douglass Hospital (JudkinsC-WDHRad-00001-00075)
  27. Wentworth Health Partners (JudkinsC-WHPIMMR-00001-00309; JudkinsC-WHPIMRad-00015-00039)

**ADDITIONAL MATERIALS**

1. Saed Confidential Documents (SAED\_SEPT222021\_SUPPL\_000001-399)